



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Roger P. Jackson

Serial No.: 09/588,924

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Filed: June 6, 2000

Group Art Unit: 3731

Exam: Daniel J. Davis

For: REMOVABLE MEDICAL IMPLANT CLOSURE FOR OPEN HEADED IMPLANTS

Kansas City, MissouriAppeal No. _____Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450**ATTENTION: Board of Patent Appeals and Interferences****APPELLANT'S BRIEF**

This brief is filed in support of the Notice of Appeal filed in this case which was forwarded to the Office on June 9, 2004.

The fees required under Rule 41.20(b)(1) and any required petition for extension of time for filing this brief and fees therefor are dealt with in the accompanying TRANSMITTAL LETTER FOR APPEAL BRIEF.

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I REAL PARTY IN INTEREST

The real party in interest in this matter is Doctor Roger P. Jackson who is the sole inventor and applicant.

II RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III STATUS OF CLAIMS

The status of the claims in this application are:

A. TOTAL NUMBER OF CLAIMS IN APPLICATION: 13

B. STATUS OF ALL OF THE CLAIMS:

1. Claims canceled: None
2. Claims withdrawn from consideration but not canceled:
None
3. Claims pending: Claims 1 to 13 (13 total)
4. Claims allowed: None
5. Claims rejected: All pending claims (13 total)

C. CLAIMS ON APPEAL:

The claims on appeal are: All pending claims (1 to 13)

IV STATUS OF AMENDMENTS

There are no outstanding amendments that have not been entered.

V SUMMARY OF INVENTION

The present invention is directed to a closure 1 for an open headed medical implant which in the illustrated embodiment is a bone screw 5 with a pair of spaced arms 15 and 16 which receive the closure 1 during use. The closure 1 both threadably closes a channel 17 formed between the arms 15 and 16 and captures a rod 6 in the channel 17. The rod 6 is further secured and locked in place relative to the bone screw 5 by tightening of the closure 1. In some instances, the closure 1 must be removed after being inserted in the bone screw 5 (see page 8, lines 1 to 22).

For inserting, the closure 1 has a driving break-off head 29 that receives a driving tool 39 to rotate and torque the head 29 once the head 29 seats in the channel 17. At a preselected torque, the closure 1 is considered to be fully seated and the rod 6 is locked in position relative to the bone screw 5 and the driving head 29 breaks away. (See page 9, line 18 through page 10, line 21).

Further, the closure 1 has a removal head 30 that is

utilized to remove the closure 1 from the bone screw 5, if that should be required. The removal head 30 is located between an externally threaded body 24 of the closure 1 and the driving head 29 and becomes exposed when the driving head 29 is broken away. (See page 11, lines 6 to 17).

The driving head 29 has an external surface that has a shape and cross section sized and shaped to receive the driving tool 39. The removal head 30 has an external surface that is sized and shaped so as to be grippable and removable by a removal tool or socket 49 (page 12, lines 1 to 13).

The key to the present invention is that the removal head 30 has an external surface that is sized and shaped different in comparison to the driving head 29, so that a surgeon during installation of the closure 1 does not inadvertently slip the driving or installation tool 39 over the removal head 30, as this is not possible because the removal head 30 is sized either too small or too big to receive and be grasped by the driving tool 39. Because the removal head 30 does not break away at a preselected torque, the closure 1 could be easily over torqued by the driving tool 39, if the driving tool grasped the removal head 30 during installation of the closure 1, leading to stripping of threads on an outer surface 26 of the closure 1 and/or other

catastrophic failure of the closure 1 and bone screw 5 implant. (See page 11, lines 6 to 23). If the implant fails, then it and possibly other implants must be disassembled, removed and replaced which is an extremely undesirable outcome. In the illustrated embodiment, the outer surface of the driving head 29 is larger and hexagonal in shape and the outer surface of the removal head 30 is smaller and square in shaped, leading to respective hexagonal and square horizontal cross sections of the driving head 29 and removal head 30.

VI ISSUES

- 1) The principal issue is whether Claims 1 to 4 and 9 to 13 are obvious and properly rejected under 35 U.S.C. 103(c) as unpatentable over U.S. Patent No. 6,193,719 to Gournay, et al.

- 2) A secondary issue is whether claims 5 to 8 are obvious and properly rejected under 35 U.S.C. 103(c) as unpatentable over Gournay, et al., in view of U.S. Patent No. 5,154,719 to Cotrel.

VII GROUPING OF CLAIMS

The pending Claims (1 to 13), while different in scope and elements, all generally include the same distinguishing features and, therefore, it is believed that all can be grouped together.

VIII ARGUMENT

It is urged that the inventions called for in Claims 1 to 13 are not obvious in view of the cited art.

Considering Claim 1, this claim calls for a closure with a break-off driving head, a removal head and an externally threaded body with the removal head located between the body and the driving head before break away of the driving head. The driving head and the removal head each have external surfaces that are different in size and shape in order to respectfully receive a driving tool and a removal tool and such that the driving tool cannot be received on the removal head. That is, the removal head is either too large to receive the driving tool or is too small to be grasped by the driving tool, but both the driving head and the removal head have surfaces that face outwardly. Further, it is specifically claimed that the external surface of the removal head has no threads thereon.

The most recent Office action dated March 23, 2004 indicates

that Claim 1 is obvious in view of Gournay, et al. It is agreed that Gournay, et al. teaches a closure for use with implants and that the closure has a break-off driving head. The illustrated embodiment of the Gournay, et al. reference further teaches that the closure has an interior print 23 (a tool receiving aperture) that becomes exposed when the driving head breaks away. Finally, Gournay, et al. makes a vague reference to a broad or basket range of prints described as follows:

"It is in this way possible to provide square, triangular, cruciform prints etc. both for clamping and disassembly, interior and exterior, and any type of fracture initiating profile." (column 4, lines 48 to 51).

It is urged that Gournay, et al. fails to teach, suggest or make obvious the claimed subject matter. In particular, Claim 1 calls for the removal head to have an exterior surface. While Gournay, et al. makes a broad basket disclosure noted above that may or may not teach an exterior print, Gournay, et al. makes no teaching of how to incorporate such an exterior print into his device. There is no such removal head shown nor is there any place to position such a removal head without using applicant's teachings that the driving head must be positioned above the threaded closure body and between the body and the driving head.

In Gournay, et al. the driving head is directly next to the closure body.

It is especially noted with respect to the basket disclosure of Gournay, et al. that the higher courts have recognized that, while a basket disclosure may disclose a wide or broad range of a subject matter, it is very possible for an inventor to find a more specific region within the broad range that in itself produces non obvious results and is patentable (see for example In re Waymouth, 499 F.2d 1273, 182 USPQ 290 (CCPA1974)). Here specifically, even if it is argued that Gournay, et al. discusses external prints and it is arguable that it does not, Gournay, et al. makes no teaching of how to apply or use such an external print in the manner claimed with the result that driving tools will not be able to grasp or grip the removal head and overtorque the closure. This is urged to be a result not taught or even foreseen by Gournay, et al.

The Office action has taken the position that the Gournay, et al. closure body can be artificially divided into upper and lower portions and that it would be obvious to place the removal surface on the exterior of the upper portion. This is urged to be counter to the teachings of Gournay, et al. In particular, the upper surface of the Gournay, et al. body is threaded and it

is not obvious to place the removal head in a threaded region. There is a limitation in Claim 1 that calls for there to be no threads on the external surface of the removal head. The Office action of March 23, 2004 on Page 4, line 3 even emphasizes this point where it is noted that:

"The exterior polyhedral shape of the removal head inherently may not have threads..."

Yet Gournay, et al. teaches threads on the upper portion of the body and does not teach how to construct the claimed device except by putting the removal head precisely where the threads are located.

The Examiner's comment that the removal head inherently may not have threads attacks the very essence of the Examiner's argument for obviousness. In particular, if the "print" of Gournay, et al. is to be moved to the exterior of the upper part of the closure body, how is this to happen without overlaying on the threads that are there? Obviously, some further teaching must be made to place the removal head between the body and the driving head. One must look to applicant's structure for this teaching.

Gournay, et al. does not teach that the driving and removal heads must be of different shape to prevent a driving tool from

inadvertently gripping the removal head.

In summary, Claim 1 is urged to distinguish over Gournay, et al. because it calls for a closure with a driving head and a removal head wherein the removal head has a different gripping surface in comparison to the driving head, such that a driving tool can not mate with or grip the removal head and that the removal head is located between the threaded body of the closure and the driving head.

Independent Claims 5 and 9 call for structure that is similar to that which has been noted above and that distinguish Claim 1 from Gournay, et al. Claim 5 was rejected on the basis of Gournay, et al. in combination with Cotrel, but Cotrel is not seen to add any of the structure missing from Gournay, et al. that is believed to distinguish the claims and, thus, Claims 5 and 9 are believed to be patentable over the art of record along with the Claims that depend from Claims 1, 5 and 9.

VIV APPENDIX

1. A closure for use in conjunction with a medical implant that is sized and shaped to operably close a channel between two spaced arms with each of said arms having an inward threaded surface; said closure comprising:
 - a) a body having an axis of rotation and a threaded cylindrical shaped radially outward surface with threads sized and shaped to be threadably mated with the threaded surfaces of the implant arms;
 - b) a break-off driving head having a first external cross section associated therewith perpendicular to the axis of rotation; said driving head having a radially outward driving surface that is polyhedral in shape and adapted to receive a driving tool for torquing said closure; said driving head being adapted to rotate and torque said body in said implant until a preselected torque occurs at which time said break-off head breaks from said body; and
 - c) a removal head having a polyhedral shape with radially outward facing engagement surfaces adapted to engage a removal tool; said removal head being located initially between said threaded

cylindrical shaped radially outward surface of said body and said driving head; said removal head having a second external cross section associated therewith perpendicular to the axis of rotation with said second cross section being different from said first cross section and being adapted to receive a removal tool for removal of said closure; said removal head outward facing surfaces being sized and shaped so as to not receive and be driven by a driving tool engaging said driving head; and said removal head second external cross section being different in size and shape from an external cross section of said body and having no threads thereon.

2. The closure according to Claim 1 wherein:

- a) said driving head is joined to said body by a breakaway region such that said driving head breaks away from said body when the preselected torque is applied to the driving head.

3. The closure according to Claim 1 wherein:

- a) said removal head is axially centered.

4. The closure according to Claim 1 wherein:

- a) said driving head cross section has a first polyhedral shape and said removal head cross section has a second polyhedral shape different from said first polyhedral shape to prevent an installation socket tool from inadvertently gripping both said driving head and said removal head during installation.

5. A medical implant system comprising:

- a) an open headed medical implant having a head formed by a pair of spaced interiorly threaded arms defining a channel therebetween sized and shaped to receive a rod member; and;
- b) a closure member including:
 - i) a body having an axis of rotation and a threaded cylindrical shaped radially outward surface with threads sized and shaped to be threadably mated with said threaded arms;
 - ii) a driving head having an external polyhedral shaped torquing surface adapted to be gripped by a torquing tool and having a first cross section associated therewith perpendicular to the axis of rotation; said driving head

operably allowing a user to rotate and torque said body with the torquing tool until a preselected torque occurs whereat said

driving head breaks from said body; and

- iii) a removal head located between said body and said driving head; said removal head having a radially outward facing removal surface sized and shaped to engage a removal tool and being free of external threads; said removal head having a second cross section associated therewith perpendicular to the axis of rotation with said second cross section being different in comparison to said driving head first cross section and sized and shaped to not receive the torquing tool, so that during torquing of said driving head, said removal head is also not inadvertently driven by the torquing tool; said removal head second cross section also being externally different than a third cross section associated with said body.

6. The implant system according to Claim 5 wherein:

- a) said driving head is joined to said body by a breakaway region such that said driving head breaks away from said body when the preselected torque is applied to the driving head.

7. The implant system according to Claim 5 wherein:

- a) said removal head is axially centered.

8. The implant system according to Claim 5 wherein:

- a) said driving head cross section has a first polyhedral shape and said removal head cross section has a second polyhedral shape different from said first polyhedral shape to prevent an installation socket tool from inadvertently gripping both said driving head and said removal head during installation.

9. A closure for use in conjunction with an open headed medical implant having a pair of interiorly threaded arms forming a channel therebetween for receiving the closure; said closure closing said channel upon being received between said arms; said closure comprising:

- a) a cylindrical shaped body with a radial outward

threaded surface sized and shaped to be threadably received between the arms of the implant; said body having an axis of rotation;

- b) a driving head axially aligned with and initially attached to said body and having a first grippable polyhedral shaped outer surface; said driving head operably rotating and torquing said body and breaking from said body at a preselected torque; and
- c) a removal head axially aligned with and attached to said body and located between said body and said driving head for removing said body from the implant; said removal head being free of external threads; said removal head being located external of said body and between said body and said driving head; said removal head having a second grippable radially outward facing outer surface; said first and second grippable outer surface being different in configuration so as to prevent a tool used with said first surface from also accidentally gripping said second surface during torquing of said driving head; said removal head having an external cross section that is different from said cylindrical body.

10. The closure according to Claim 9 wherein:

- a) said driving head is attached to said body at a breakaway region that provides for said driving head to break from said body when the preselected torque is applied to said driving head.

11. The closure according to Claim 9 wherein:

- a) said driving head and said removal head have different shaped cross sections perpendicular to said axis of rotation.

12. The closure according to Claim 9 wherein:

- a) said driving head is larger in cross section in comparison to said removal head.

13. The closure according to Claim 9 wherein:

- a) each of said driving head and said removal head have a number of faces forming a polyhedral cross section; said driving head having a different number of faces in comparison to said removal head.

CONCLUSION

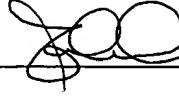
Gournay, et al. fails to teach placing the removal head between the threaded closure body and the driving head and for this reason it is urged that Gournay, et al. by itself does not make the claimed subject matter obvious. No combination of Gournay, et al. with Cotrel or any other reference of record teaches placing different sized or shaped external surfaces on a driving head and a removal head so that the removal head can not be inadvertently grasped by a driving tool. Finally, Gournay, et al. fails to teach that the external surface of the removal tool must be placed in a non threaded region, which is called for in the claims and recognized as inherently required by the Examiner.

Therefore, it is urged that Claims 1 to 13 are not obvious in view of Gournay, et al. or this reference in combination with Cotrel.

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November 9, 2004

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